IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation	)	**19-MD-2875 (RBK-SAK)**
	)	**Daubert ORDER 2 / Accompanying Opinion: REGARDING PARTIES' MOTIONS TO PRECLUDE TESTIMONY BY EXPERT WITNESSES**
This document applies to all cases.	)	

KUGLER, District Judge:

THIS MATTER HAVING COME BEFORE the Court upon the parties' motions *in limine* pursuant to Federal Rules of Evidence 702, 403, and 104 to preclude testimony of various experts, especially upon:

Motions by all Plaintiffs to preclude the testimony of Defendants' experts:

Michael B. Bottorff, Pharm.D.: (Doc. Nos. 1712, 1789, and 1862);

George E. Johnson, Ph.D.: (Doc. Nos. 1711, 1796, and 1856);

THE COURT HAVING SET FORTH PROCEDURE for two *Daubert*[1] hearings, which:

Required those experts selected to testify at the *Daubert* hearings to submit sworn certifications as to the accuracy of their opinions ["the Certifications"]; and

Authorized that the *Daubert* hearings would elicit only cross-examination testimony relating to only the opinions in the Certifications;

THE COURT HAVING HELD a first *Daubert* hearing on 2 March 2022 for the Cross-Examination of Plaintiffs' selected experts and, on 4 March 2022, issued *Daubert* Order 1 (Doc. No. 1958); and

PLAINTIFFS CANCELLING the second *Daubert* hearing and therefore not cross-examining Defendants' Experts Bottorff and Johnson;

[1] Following *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786 (1993), in which the Supreme Court required federal district courts to make a "preliminary assessment" of the admissibility of expert testimony. *Id.* at 2796.

THE COURT HAVING CONSIDERED the parties' briefs, oppositions and replies in the above Motions, and the submitted Certifications, for good cause shown, and for the reasons expressed herein:

IT IS HEREBY ORDERED regarding the Motions to Preclude the Testimony of Defendants' Experts**:**

As to the opinions of **Michael B. Bottorf,** Pharm.D., Plaintiff's Motion to Preclude (Doc. 1712) is **DENIED**; and

As to the opinions of **George E. Johnson,** Ph.D., Plaintiff's Motion to Preclude (Doc. 1711) is **DENIED.**

DISCUSSION

At the first *Daubert* hearing held on 2 March 2022, defense counsel cross-examined three of plaintiffs' expert witnesses. At the conclusion of the hearing, the Court read into the record its decision on those *Daubert* motions as well as other motions filed by both sides. (Doc. No. 1954). The second *Daubert* hearing, scheduled for 15 March 2022, was to cross-examine the remaining defense experts, Michael B. Bottorff, Pharm.D., and George E. Johnson, Ph.D.

However, plaintiffs' lead counsel, Adam Slater, Esq., emailed the court on 11 March 2022 that plaintiffs no longer wished to cross-examine Dr. Bottorff or Dr. Johnson, and the second *Daubert* hearing was cancelled. What follows here is the Court's decision on plaintiffs' two remaining motions to preclude: the opinions of Michael B. Bottorff and George Johnson.

Michael B. Bottorff, Pharm.D.

Dr. Bottorff's Declaration[2] (Doc. No. 1929-1) dated 24 February 2022 addresses many of the objections in plaintiffs' motion to preclude. The Court assumes he will testify at trial that his opinion is: because of the capacity of the liver to completely metabolize what Dr. Bottorff describes as the trace levels of NDMA and NDEA in the contaminated Valsartan,

[2] As reported in *Daubert* Order 1 (Doc. No. 1958), the Court's procedure for the *Daubert*[2] hearings was this: those experts selected to testify at the *Daubert* hearings were required to submit sworn certifications as the accuracy of their opinions ["the Certifications"], and at the *Daubert* hearings, the opposing party could elicit from each selected expert only cross-examination testimony relating to only their opinions in the Certifications.

virtually no NDMA or NDEA could have or did reach the systemic circulation or organs beyond the liver. In his deposition, Dr. Bottorff stated he was only looking at research that informed on doses that did not cause cancer. In his Declaration (Doc. No. 1929-1), however, Dr. Bottorff states he examined all animal studies and does acknowledge there are animal studies that did demonstrate cancers associated with the intake of NDMA/NDEA. Although I fully expect Dr. Bottorf will be vigorously cross-examined at trial about how and whether NDMA ingested amounts overload the liver's metabolization process, I find his methodology acceptable.

Dr. Bottorff's dose conversion methodology is not what the FDA or other government health agencies across the world use. But, there is no showing that his conversion to 70 kilograms to account for what he terms a normal size human adult is not an accepted methodology. That is, there is no showing that the FDA method is the only acceptable methodology. Dr. Bottorff explains that he never attempted to calculate a dose that would or could cause cancer in humans because, in his opinion, the amounts of NDMA or NDEA contaminants in even the highest dosage of Valsartan would never approach a cancer-causing amount in humans. (Bottorff Declaration, Doc. No. 1929-1, ¶17)

In their motion to preclude (Doc. No. 1712-2), plaintiffs complain Dr. Bottorff lacks sufficient knowledge of NDMA metabolism and relies on " underpowered" studies. Again, these perceived weaknesses in the substance of his opinion can be more thoroughly disputed during cross-examination. Despite such disputed weaknesses in his opinion, the methodology that grounds Dr. Bottorff's opinion is acceptable in the relevant scientific community.

Accordingly, plaintiffs' motion to preclude (Doc. No. 1712) the testimony of Dr. Michael Bottorff is **DENIED.**

George E. Johnson, Ph.D.

As to Dr. George E. Johnson, the dispute centers on his benchmark dose methodology [" BDM"] to calculate that amount of ingested NDMA/NDEA likely to cause cancer. Clearly this is not the methodology used by many scientists, which Dr. Johnson addresses extensively in his Declaration beginning at ¶3. Doc. No. 1929-2.

While possibly not the best methodology by which to measure the probable cancer-causing ingestion amount of NDMA/NDEA in contaminated valsartan, BDM is nonetheless used by some in the relevant scientific community. The PETO study relied on or cited by most parties' experts may or not entirely support Dr. Johnson' s conclusion. But, once again, the

jury will have to decide--as for all the experts--whether an individual expert should or not have relied on certain studies.

Like all other defendants' experts, Dr. Johnson does not conduct research independent of this litigation, which is not necessarily fatal to his conclusions. I'm confident plaintiffs' counsel will point that out to the jury.

As to his threshold and conceptual assumptions, Dr. Johnson addresses these in his Declaration at ¶14. Doc. No. 1929-2. He uses the average weight of the plaintiffs for whom he had data. As with Dr. Bottorff's methodology, it is not unacceptable even though not the method used by the FDA and other governmental health agencies. In particular, Dr. Johnson does not use the TD- 50 linear extrapolation method used by all government health agencies, including the FDA and the WHO. Though fertile ground for cross-examination, the TD- 50 method has not been shown to be the only acceptable methodology by which to calculate a dosage of NDMA contaminant statistically likely to induce human cancer.

Dr. Johnson's work for large pharmaceutical companies may influence the jury that his opinion is biased in these companies' favor. But as defendants' counsel recognized, this potential bias goes to the weight of the evidence, not to admissibility. In in his Declaration, ¶17, Dr. Johnson explains why he thinks dietary studies are not significant and at ¶9 why he believes the human DNA repair mechanism completely eliminates mutations below the PDG. (Doc. No. 1929-2). The jury need not accept any of his opinions, but these are sufficiently grounded in recognized scientific methodology.

Accordingly, plaintiffs' motion to preclude (Doc. No. 1711) the testimony of defendants' expert Dr. George Johnson is **DENIED**.

Dated: 17 March 2022

s/ Robert B. Kugler
Honorable Robert B. Kugler
United States District Judge